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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/869,814
Filing Date: July 05, 2001
Appellant(s): GARCIA-LADONA, FRANCISCO JAVIER

Jason D. Voight
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/9/06 appealing from the Office action mailed 2/25/04.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

University of Rochester, v. G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc. (03-1304).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-32 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is set forth in a prior Office Action, mailed on 25 February 2004, and is paraphrased therein:

The present claims are directed to a method for treating migrainous cerebrovascular disorders by administering at least one binding partner for a 5-HT5-receptor with specific binding affinity for the receptor. The present specification, however, does not disclose any of such binding partner meeting the limitations of the claims. In a subsequent Declaration under 37 CFR 1.132 filed on 24 November 2003 (the Garcia-Ladona declaration), one such compound, HK02-01, was disclosed, which exhibits a binding affinity for 5-HT5A receptor more than 10-times higher than its affinity for the 5-HT1D receptor (item 3 of the declaration), and significantly decreases spreading velocity in retinal spreading depression test, a model for evaluating the efficacy of compounds in the treatment of migraine (items 6 to 8). However, this compound was not disclosed in the specification as originally filed. Thus, no binding partners for 5-HT5 receptor meeting the limitations of the claims were ever identified or particularly described by the applicants in the specification as originally filed. It is required that the patent

specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In a recent case law, *University of Rochester, v. G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc.* (03-1304), the Court recites from *In re Ruschig*, 379 F.2d 990 (CCPA 1967):

> [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] . . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

The Court further states that "regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding

a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment." Id."

In the instant situation, the present specification does not disclose the structure or physical properties of any compounds encompassed by the claims, and required to practice the claimed methods, and that the structure of such compounds cannot be deduced from any known structure-function correlation, even considering the knowledge of one skilled in the art. The disclosure of HK02-01 in the 132 declaration does not remedy this failure since adequate written description is analyzed as of the filing date.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims fail to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

(10) Response to Argument

At pages 6-7 of the Brief, the appellant argues that the claims in US6,048,850, the subject of the *University of Rochester* case cited by the examiner, were drawn to a method for selectively inhibiting PGHS-2 activity by administering a compound selectively inhibiting activity of the PGHS-2 gene product, that in contrast, the present claims are directed to a method for treating migrainous cerebrovascular diseases such as migraine, thus, the subject matter of the claims is not simply confined to selectively inhibiting 5-HT5 receptor activity by administering

compounds selectively inhibiting activity of the 5-HT5 receptor. Appellants argument has been fully considered, but is not deemed persuasive because the major issue is not what the compound does, i.e., selectively inhibiting or activating the receptor activity, rather, the major issue is what the compound is, or what is the structural feature of the compound. As clearly state by the Court in *University of Rochester, v. G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc.* (03-1304), the Court recites from *In re Ruschig*, 379 F.2d 990 (CCPA 1967): "[T]he disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described".

The appellant further argues, at page 7 of the Brief, that the present invention teaches for the first time that cerebrovascular diseases such as migraine can be effectively treated with binding partners for the 5-HT5 receptor, thus, it is the relationship between 5-HT5 binding affinity and the treatment of certain diseases which represent the contribution the present invention makes over the prior art, and that the '850 patent does not make such a contribution. Appellants argument has been fully considered, but is not deemed persuasive because it is irrelevant as it is the compound itself used in the method, which identity has to be described. Even if the present application revealed a novel relationship between 5-HT5 binding affinity and the treatment of migraine, it does not entitle the claims to a lower standard of compliance with the written description requirement of 35 U.S.C. §112, first paragraph.

The appellant further argues, at page 7 of the Brief, that indeed, as held in *Enzo*, disclosure of a nucleic acid can support a claim to nucleic acid that hybridize to it. This argument has been fully considered, but is not deemed persuasive because the nucleic acid case in *Enzo* is completely different from the instant situation and does not apply here. The principle

of complementary pairing (or "hybridizing") for nucleic acid has been well established, and notoriously old in the art, and it is as simple as A-T(U) and C-G. Receptor-ligand binding is not the analog of nucleic acid hybridization. The prior art has not established that knowing the sequence of a receptor would automatically lead to a structure of its ligand.

The appellant further argues, at page 7 of the Brief, that the present specification sets forward several "animal models based on mechanisms which can underlie the formation of migraine" disorders, and they are described in detail in the prior art, and that testing identified 5-HT5 binding partners using these models would be a matter of routine to the appropriately skilled artisan. Appellants argument has been fully considered, but is not deemed persuasive because the issue is not whether testing identified 5-HT5 binding partners is routine or not, rather, the most important issue here is that *there is no* 5-HT5 binding partners meeting the limitations of the claims were ever identified or particularly described in the instant specification, and merely one without its chemical structure, HK02-01, was disclosed in a subsequently filed Declaration. Although one of skill in the art could test identified 5-HT5 binding partners for activity, the structures of such binding partners would be required for making the candidate compounds before the binding partners can be identified and tested for functional activity. Such structures have not been described in the instant specification. Furthermore, the instant claims are directed to a method of treatment using a 5-HT5 binding partner, not a method of screening a 5-HT5 binding partner, without an identified 5-HT5 binding partner, or even potential candidates, the conception cannot be achieved regardless of the complexity or simplicity of the method of testing activity.

At pages 7-8 of the Brief, the appellant argues that the Garcia-Ladona declaration of record demonstrates the efficacy of 5-HT5 binding partners of the appropriate binding affinities relative to 5-HT1D affinity, and supports the presumption that one of ordinary skill in the art would be able to carry out the presently claimed invention based on the specification and knowledge in the art. This argument has been fully considered, but is not deemed persuasive because as addressed above, the declaration merely discloses *one* such binding partner without its chemical structure. There is no evidence showing that those cited in the specification and known in the art for the treatment of migraine meet the limitations of the claims. Thus, the instant application does not provide representative species to support the broad genus in the claims, which recite no structural limitation for the compound that would be a 5-HT5 binding partner with the specified affinity.

At page 8 of the Brief, the appellant argues that the decision in *In re Bundy*, 642 F2d 430, 434, 209 USPQ 48, 52 (Fed. Cir. 1981) is considered to be quite relevant to the present fact situation as the Court states: early filing of an application with its disclosure of novel compounds which possess significant therapeutic use is to be encouraged, and requiring specific testing of the thousands of prostaglandin analogs encompassed by the present claim in order to satisfy the how-to-use requirement of §112 would delay disclosure and frustrate, rather than further, the interests of the public. Appellants argument has been fully considered, but is not deemed persuasive because, as addressed above, the matter is not testing of the thousands of compound, or satisfying the how-to-use requirement, rather, it is that there is nothing to test because one of skilled in the art cannot envision the detailed chemical structure of the encompassed "binding partner for a 5-HT5-receptor", and therefore, cannot even make potential candidates for such

binding partners as no chemical structure of any of such binding partners was ever described by the instant application.

The present claims are clearly "reach-through claims", wherein the specification has adequate written description for methods of screening for compounds that are binding partners for a 5-HT5 receptor with particular activities. However, there is inadequate written description for the compounds themselves, or methods of administering the compounds.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

Dong Jiang, Ph.D.
April 6, 2006

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